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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,314	02/06/2002	Michael T. Trese	TMT-10902/04	8834

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EXAMINER	
DESANTO, MATTHEW F	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,314	TRESE ET AL.	
	Examiner	Art Unit	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-21 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-21 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The new range is supported by the specification due to the amendments and remarks made by applicant.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7, 9, 10, 13-18, 20, 21, and 24 are under 35 U.S.C. 103(a) as being unpatentable over by Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye. Trese et al. discloses using 0.4 IU, but fails to disclose a size of dose smaller then 0.4 IU.

AT the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Trese et al. because it is well known in the medical field art to vary the does size that will be injected into a patient, since medication usually depends on the size of the patient as well as the area in which the injection will occur. This concept is well known in the research art and can be seen in the previous cited prior art (Entire reference). There is also a

lack of criticality in the range claimed; therefore it would only take routine skill in the art to modify the dose of a medication through routine experimentation.

4. Claims 8, 19, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620) as applied to the claims above, and further in view of Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610).

Trese et al. (Ophthalmology) discloses the claimed invention but fails to specifically point out the use of a plasmin inhibitor and the actual size of the needle being used to remove the liquefaction that occurred in the eye.

Trese et al. (American Academy of Ophthalmology) discloses the use of a plasmin for the liquefaction of the eye as well as the use of small gauge needles for sucking the material out of the eye (page 1610 2nd Column, 1st paragraph) and the use of a plasmin inhibitor to reduce to the activity of the plasmin that was injection into the eye (surgical techniques).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Trese et al. with Trese et al. because Trese et al. (American) provides further explanation as to why those steps are necessary. Trese et al. (American) also discloses the level of skill in the medical art since it is well known in the art to perform these steps. Trese et al. (America) provides motivation to use a small gauge so that there will be a smaller hole in the eye from the needle, and the plasmin inhibitor was used to control the amount of time and effectiveness of plasmin.

Response to Arguments

5. Applicant's arguments filed on 4/17/07 have been fully considered but they are not persuasive with regards to the prior art rejections, but are persuasive with regards to the 112 Rejection.

6. The examiner has read through applicant's remarks, which seem to support the examiner's assertion of modifying the prior art because of the lack of criticality of the range of plasmin and how this range can be modified depending on the circumstance and condition of a patient. This is usually determined by a physician or a person that is treating the patient. According to applicant's remarks in the last paragraph on page 7 to 8 the amount of plasmin being used to treat the patient depends on several factors and that it would only take routine experimentation to determine this concentration and the range falls between .01-5 units. Thus supporting the examiner assertion of modifying the plasmin concentration by routine experimentation.

7. The examiner is basing the rejections that it would have been obvious to change the size and concentration of the plasmin that would be injected in an eye due to the lack of criticality of the specific range being claimed. According to MPEP section 2144.05 "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." Since no such evidence has been submitted the examiner maintains his rejections.

8. The examiner logic of vary the concentration and size of a dose is due to the fact of routine experimentation that occurs when conducting research and treating a patient. This is well

known in the medical art and references can be supplied if needed. There are several references of record that disclose varying the concentration to find an optimal range of effectiveness.

9. The applicant draws the attention of page 5, line 5 in the specification for critical of the 0.4 IU for the invention, but the examiner doesn't find this paragraph to be sufficient because the paragraph teaches varying the dose from subject to subject and that "in a pediatric patient where the volume of the eye is significantly smaller, a dose of 0.4 units may result in facilitating posterior vitreous detachment." There is no support that this dose is critical for treatment or is the optimal dose.

10. With regards to the references teaching away from the claimed invention, the examiner disagrees with the interpretation of the prior art. Both references teach liquefaction of the eye (at least to a certain degree) at an adjacent range to the claimed range. So it would be convincible to perform routine experimentation with the prior art depending on the size of the eye in which the plasmin is going to be delivered. Since the prior art showed some success at 0.4 units and thus wouldn't discourage one of ordinary skill in the art to perform routine experimentation of the prior art.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
June 23, 2007